UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

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GEORGE BEITZEL, KATHERINE KRAIG, and SHARON GOLDSTEIN, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

XAVIER BECERRA, Secretary of Health and Human Services,

Defendant.

No. 2:23-cv-01932 WBS DB

MEMORANDUM AND ORDER

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Plaintiffs George Beitzel, Katherine Kraig, and Sharon Goldstein bring this putative class action for declaratory and injunctive relief against Xavier Becerra, the Secretary of Health and Human Services, regarding a series of denied Medicare claims. (First Am. Compl. ("FAC") (Docket No. 19).) Plaintiffs assert two legal claims: violation of due process (Claim 1), and failure to waive liability for Medicare Part B drugs (Claim 2). Beitzel further asserts a violation of the Rehabilitation Act, 29

U.S.C. § 794(a) (Claim 3). Defendant now moves to dismiss. (Mot. (Docket No. 29).)

The parties are familiar with the allegations of the complaint, and the court accordingly will not recite them in detail here. Essentially, it is alleged that plaintiffs are Medicare beneficiaries who received injections of a drug called Stelara in an outpatient clinical setting. The providing of Stelara in that setting was covered by Medicare Part B, which pays for outpatient drugs administered incident to a practitioner's services. In 2021, defendant ended Part B coverage for Stelara by designating it "usually self-administered." However, plaintiffs were not notified of this change by anyone, continued going to the doctor's office to get Stelara injections, and were billed substantial sums for Stelara that they received at the doctor's office.

## I. Jurisdiction

Before addressing the merits of plaintiffs' legal claims, the parties assert a slew of statutory and constitutional jurisdiction arguments. For the reasons discussed below, the court concludes that (1) it has subject matter jurisdiction over Beitzel's December 2019 Medicare claim, but no other Medicare claims; and (2) Beitzel has standing to seek relief for past injuries caused by Stelara's addition to the SAD List, but not to seek relief for any prospective injuries that might be caused by other drugs being listed in the future.

### A. Subject Matter Jurisdiction Under 42 U.S.C. § 405(g)

#### 1. Failure to Exhaust Administrative Remedies

Section 405(g) of the Medicare statute vests this court

with jurisdiction over claims arising under Medicare[1] [2], but only after a plaintiff exhausts all available administrative remedies. 42 U.S.C. § 405(g); see Odell v. U.S. Dep't of Health & Hum. Servs., 995 F.3d 718, 722 (9th Cir. 2021) ("the Medicare statute requires exhaustion of administrative remedies as a prerequisite to bringing an action in court"). The exhaustion requirement applies on a claim-by-claim basis. See id. at 723 ("[p]roperly channeling one claim -- or even several claims -- [through administrative appeals] does not permit a plaintiff to resolve other claims or causes of action that have not been channeled").

Of the eight Medicare claims challenged by the three plaintiffs through the Medicare administrative process, only Beitzel's December 2021 Medicare claim has been properly exhausted. (See FAC ¶ 81-84, 72-83 & n.8, 93-99; see also Opp'n (Docket No. 32) at 15 ("Ms. Kraig and Ms. Goldstein have not yet completed Medicare's administrative review process . . . .").)

2. No Waiver of Exhaustion

Plaintiffs argue that the court should waive the exhaustion requirement as to their non-exhausted Medicare claims. A court may do so if a plaintiff can show that the non-exhausted claim is "(1) collateral to a substantive claim of entitlement (collaterality), (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability), and (3) one

[1] Neither party disputes that plaintiffs' claims arise under the Medicare statute. (See Mot. at 18; Opp'n at 13-14.)

[2] 42 U.S.C. § 405(g) is the Social Security Act's judicial review provision. 42 U.S.C. § 1395ff(b) incorporates this provision into the Medicare statute, 42 U.S.C. § 1395 et seq.

whose resolution would not serve the purposes of exhaustion (futility)." Kaiser v. Blue Cross of California, 347 F.3d 1107, 1115 (9th Cir. 2003).

The court will not waive the exhaustion requirement because plaintiffs fail to satisfy at least the collaterality prong. While plaintiffs assert that they "do not ask the Court to resolve any issue relating to their individual claims" for benefits (see Opp'n at 16), their complaint and opposition undercut that assertion. (See FAC at 34 (seeking a permanent injunction "[w]aiving the liability of Plaintiffs . . . for Part B medications they received or receive"); Opp'n at 17 ("The requested relief would allow [Kraig] to seek a refund of the thousands of dollars she paid the hospital"); id. at 22 ("[plaintiffs'] due process claim includes waiving the liability of beneficiaries who did not receive adequate notice before receiving a drug that was [removed from Part B coverage]").) Because plaintiffs' legal claims are "inextricably intertwined" with their claims for Medicare benefits, they cannot be deemed "collateral." See Johnson v. Shalala, 2 F.3d 918, 921 (9th Cir. 1993); see also Kaiser, 347 F.3d at 1116 n.4 ("all inextricably intertwined claims must first be raised in an administrative process").

Accordingly, no waiver applies.

B. No Alternative Bases for Jurisdiction for Non-Exhausted Claims

As a final resort, plaintiffs argue that the court still has jurisdiction over plaintiffs' non-exhausted Medicare claims under 28 U.S.C. § 1361 (mandamus) and § 1331 (federal

question). (See Opp'n at 20-21.)

The court disagrees. The text of Section 405(h) plainly makes the court's jurisdiction under Section 405(g) exclusive: it states that no final administrative decision "shall be reviewed by any person, tribunal, or governmental agency except as herein provided." 42 U.S.C. § 405(h). See also Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 10 (2000) ("Section 405(h) purports to make exclusive the judicial review method set forth in § 405(g)"); Do Sung Uhm v. Humana, Inc., 620 F.3d 1134, 1140 (9th Cir. 2010) (§ 405(g) is "the sole avenue for judicial review for claims arising under the Medicare Act") (citations omitted); Kaiser v. Blue Cross of California, 347 F.3d 1107, 1111 (9th Cir. 2003) ("Jurisdiction over cases 'arising under' Medicare exists only under 42 U.S.C. § 405(g), which requires an agency decision in advance of judicial review.").[3]

Accordingly, the court lacks subject matter jurisdiction generally to adjudicate Kraig's and Goldstein's legal claims and will therefore dismiss the claims of Kraig and

[3] To the extent that plaintiffs cite binding and contrary cases establishing alternative bases for jurisdiction, the court observes that those cases long predate the Ninth Circuit's more recent and expansive holdings in Do Sung Uhm and Kaiser. To the extent that plaintiffs argue for a narrow exception to Section 405(g)'s bar, plaintiffs fail to establish that "application of § 405(h) . . . would mean no review at all" because an administrative channel for review and redress clearly exists here -- one under which plaintiffs have even found some measure of success. Shalala, 529 U.S. at 19. See Sensory Neurostimulation, Inc. v. Azar, 977 F.3d 969, 983-84 (9th Cir. 2020) ("no review at all" exception cannot apply where "an administrative channel for review exists").

Goldstein.[4] This action will proceed on Beitzel's fully-exhausted December 2021 Medicare claim as the main factual predicate for his legal claims.

C. Article III Standing

Defendant challenges Beitzel's standing to bring his legal claims to the extent that he requests prospective remedies related to drugs other than Stelara.[5]

Federal subject-matter jurisdiction extends only to "Cases" and "Controversies." U.S. Const. art. III, § 2. A plaintiff satisfies this jurisdictional requirement only if he has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016).

Beitzel has not alleged that he suffered an injury in fact as to any other drug than Stelara. His assertions about his "ongoing concerns regarding Medicare's SAD List policies" and "likei[ihood] that [he] will require additional medications that are furnished incident to a practitioner's service" (Opp'n at 24-25) are too remote and speculative to satisfy the constitutional requirement that "threatened injury must be certainly impending." Clapper v. Amnesty Int'l USA, 568 U.S. 398, 409 (2013) (internal quotation marks and alteration omitted). This reasoning applies

[4] The court accordingly need not address defendant's improper venue argument as to Kraig and Goldstein. (See Mot. at 20.)

[5] Neither party disputes that Beitzel has standing to seek relief for Stelara injections that were denied coverage. (See Opp'n at 23-24; Reply (Docket No. 33) at 8.)

with special force when plaintiffs' complaint does not identify a single other drug currently covered by Part B that they currently need or anticipate needing in the very near future.

Accordingly, the court will consider Beitzel's legal claims only to the extent that they seek relief for past injuries caused by Stelara being added to the SAD List without adequate notice.

II. Rule 12(b)(6)

Finally, the court examines the underlying merits of Beitzel's legal claims. In so doing, the court construes all factual allegations as true and grants Beitzel every reasonable factual inference. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

A. Due Process (Claim 1)

In order to state a due process claim, a plaintiff must allege a deprivation of a constitutionally protected property interest and a denial of adequate procedural protections. Kildare v. Saenz, 325 F.3d 1078, 1085 (9th Cir. 2003); see Bd. of Regents v. Roth, 408 U.S. 564, 569-70 (1972).

Regarding adequacy, the Ninth Circuit has specifically rejected the idea that the Due Process Clause requires prior notice before enacting and enforcing laws of general applicability. See, e.g., Halverson v. Skagit County, 42 F.3d 1257, 1260 (9th Cir. 1994) ("[G]overnmental decisions . . . not directed at one or a few individuals do not give rise to the constitutional procedural due process requirements of individual notice and hearing; general notice as provided by law is sufficient."); Gallo v. U.S. Dist. Ct. For Dist. of Arizona, 349

F.3d 1169, 1182–83 (9th Cir. 2003) ("Since the amended rule affects a large number of people, as opposed to targeting a small number of individuals based on individual factual determinations, Gallo's claim that he is entitled to individual notice and an opportunity to be heard fails because the amended legislative rule does not 'give rise to constitutional procedural due process requirements.'" (citing Christensen v. Yolo County Bd. of Supervisors, 995 F.2d 161, 166 (9th Cir. 1993))). See generally Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 441, 445 (1915) ("Where a rule of conduct applies to more than a few people, it is impracticable that everyone should have a direct voice in its adoption.") (Holmes, J.).

The addition of Stelara to the SAD List clearly is a decision of general applicability, which was accompanied by accordingly appropriate general notice to the public. Beitzel alleges that Stelara was added to the SAD List in at least two out of twelve nationwide MAC jurisdictions. (FAC ¶¶ 37, 63, 91, 106.) Beitzel also describes in great detail a nationwide, years-long advocacy campaign to stop Stelara and other drugs from being added to the SAD Lists. (Id. ¶¶ 123-31.) Finally, the SAD Lists including Stelara were made public back in 2020 before taking full effect in 2021. (Id. ¶ 127 & Local Coverage Articles A53032, A53021.)

While it does appear unfair to expect Beitzel, or any Medicare beneficiary generally, to keep abreast of such complex regulatory developments in order to avoid astronomical medical bills, not every unfairness rises to the level of a constitutional violation. Beitzel can point to no authority

other than the Due Process Clause for his proposition that individualized notice was due. And for the reasons discussed above, the Due Process Clause alone cannot vindicate him here.

Accordingly, the court is constrained to dismiss the due process claim.

B. Failure to Waive Liability Under Medicare Statute (Claim 2)

The Medicare statute directs defendant to waive beneficiaries' liability incurred due to a denial of coverage in certain circumstances. See 42 U.S.C. § 1395pp(a)-(b) (requiring wavier of liability or indemnity where both individual and healthcare provider did not and could not have known that Part B would not cover given expense). However, this authority is expressly limited to certain enumerated categories of denied claims. Id. § 1395pp(a) (services that are not reasonable and necessary, 42 U.S.C. § 1395y(a)(1); custodial care, id. § 1395y(a)(9); and certain home-health and hospice services, id. § 1395pp(g)).

Beitzel's Stelara injection was denied coverage under Part B because Stelara is now deemed "usually self-administered." See 42 U.S.C. §§ 1395k(a)(1), 1395x(s). (See also FAC ¶¶ 3, 32, 63.) This is not one of the enumerated categories, and defendant accordingly has no statutory authorization to waive liability for claims denied under that basis.[6]

[6] The court is not persuaded by Beitzel's attempt to couch "usually self-administered" denials as medical necessity determinations, 42 U.S.C. § 1395y(a)(1). MACs rely on empirical statistical information, certain presumptions based on a drug's delivery mechanism, and conditions related to the drug to determine whether a drug is usually self-administered. (FAC ¶¶

Accordingly, the court must also dismiss this claim.

C. Rehabilitation Act § 504 (Claim 3)

Section 504 of the Rehabilitation Act, 29 U.S.C. § 701 et seq., provides that "[n]o otherwise qualified individual with a disability . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination . . . under any program or activity conducted by any Executive agency." 29 U.S.C. § 794(a). A defendant may violate Section 504 if it "denies a qualified individual with a disability a reasonable accommodation that the individual needs in order to enjoy meaningful access to the benefits of public services." Mark H. v. Hamamoto, 620 F.3d 1090, 1097 (9th Cir. 2010).

Beitzel argues that defendant's recharacterization of Stelara as a usually self-administered drug deprived him of "meaningful access to [his] Medicare benefits." (See FAC ¶ 150; Opp'n at 32-33.) Accordingly, he requests a reasonable modification for "Medicare-covered administration of [Stelara] by a qualified health care professional." (FAC ¶ 150.)

Because Beitzel has not alleged that he was deprived of Medicare-covered administration of Stelara, the court concludes he has failed to allege sufficient facts that show a deprivation of meaningful access to Medicare benefits. At oral argument, the parties clarified that the Part B coverage of Stelara

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33-35.) MACs also make this determination on a drug-by-drug basis, not a beneficiary-by-beneficiary basis. (Id. ¶ 35.) See also Glassman v. Azar, No. 1:18-CV-00945LJO BAM, 2019 WL 2917990, at *4 (E.D. Cal. July 8, 2019) ("Section 1395pp does not apply every time a service is not medically necessary.").

administration was not at issue, but rather that Part B coverage for obtaining Stelara was. (See also FAC ¶ 29 ("Part B pays for drugs and biologicals furnished incident to the service of a physician (or other practitioner)."") (emphasis added); Docket No. 27-3 at 7 (partial Part B coverage for $252 charged for Stelara administration, but no Part B coverage for $43,543.47 charged for 1mg of Stelara).)

Beitzel acknowledges that he, like other patients dependent on Stelara, has continued coverage for obtaining Stelara under Part D. (See Opp'n at 32 ("Mr. Beitzel and other disabled beneficiaries obtain coverage from Part D at least theoretically . . . .").) Absent any additional allegations that Beitzel is precluded from obtaining Stelara on his own through Part D, as he presently does (see FAC ¶ 86), and then getting Stelara administered at a doctor's office through Part B, the court cannot conclude that Beitzel has lost meaningful access to his Medicare benefits.

Accordingly, the court will also dismiss this claim. Beitzel will be given leave to amend this claim if he can allege additional facts showing that he was meaningfully deprived of Medicare-covered administration of Stelara.

IT IS THEREFORE ORDERED that defendant's motion to dismiss (Docket No. 29) be, and the same hereby is, GRANTED. Plaintiffs are given 20 days from the date of this Order to file an amended complaint if they can do consistent with this Order.

Dated: April 19, 2024

WILLIAM B. SHUBB
UNITED STATES DISTRICT JUDGE